

## § 725.27

(1) Data previously submitted to EPA. (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the new submission includes: the office or person to whom the data were submitted; the date of submission; and, if appropriate, a standard literature citation as specified in § 725.160(a)(3)(ii).

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the new submission and any claim of confidentiality, under § 725.80.

(2) Efficacy data. This part does not require submission of any data related solely to product efficacy. However, including efficacy data will improve EPA's ability to assess the benefits of the use of the microorganism. This does not exempt a person from submitting any of the data specified in § 725.160 or 725.260.

(3) Non-U.S. exposure data. This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

## § 725.27 Submissions.

Each person who is required to submit information under this part must submit the information in the form and manner set forth in the appropriate subpart.

(a) Requirements specific to MCANs are described in §§ 725.150 through 725.160.

(b) Requirements specific to TERAs are described in §§ 725.250 through 725.260.

(c) Requirements specific to test marketing exemptions (TMEs) are described in §§ 725.350 and 725.355.

(d) Requirements specific to Tier I and Tier II exemptions for certain general commercial uses are described in §§ 725.424 through 725.470.

(e) Additional requirements specific to significant new uses for microorganisms are described at § 725.950.

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### § 725.28 Notice that submission is not required.

When EPA receives a MCAN or exemption request, EPA will review it to determine whether the microorganism is subject to the requirements of this part. If EPA determines that the microorganism is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture, import, or processing of the microorganism and that the submission is not needed.

### § 725.29 EPA acknowledgement of receipt of submission.

(a) EPA will acknowledge receipt of each submission by sending the submitter a letter that identifies the number assigned to each MCAN or exemption request and the date on which the review period begins. The review period will begin on the date the MCAN or exemption request is received by the Office of Pollution Prevention and Toxics Document Control Officer.

(b) The acknowledgement does not constitute a finding by EPA that the submission is in compliance with this part.

### § 725.32 Errors in the submission.

(a) Within 30 days of receipt of the submission, EPA may request that the submitter remedy errors in the submission. The following are examples of such errors:

(1) Failure to date the submission.

(2) Typographical errors that cause data to be misleading or answers to any questions to be unclear.

(3) Contradictory information.

(4) Ambiguous statements or information.

(b) In the request to correct the submission, EPA will explain the action which the submitter must take to correct the submission.

(c) If the submitter fails to correct the submission within 15 days of receipt of the request, EPA may extend the review period.

### § 725.33 Incomplete submissions.

(a) A submission under this part is not complete, and the review period does not begin, if:

(1) The wrong person files the submission.

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(2) The submitter does not attach and sign the certification statement as required by § 725.25(b).

(3) Some or all of the information in the submission or any attachments are not in English, except for published scientific literature.

(4) The submitter does not provide information that is required by sections 5(d)(1)(B) and (C) of the Act and § 725.160 or 725.260, as appropriate.

(5) The submitter does not provide information required by § 725.25, 725.155, 725.255, 725.355, or 725.455, as appropriate, or indicate that it is not known to or reasonably ascertainable by the submitter.

(6) The submitter has asserted confidentiality claims and has failed to:

(i) Submit a second copy of the submission with all confidential information deleted for the public file, as required by § 725.80(b)(2).

(ii) Comply with the substantiation requirements as described in § 725.94.

(7) The submitter does not include any information required by section 5(b)(1) of the Act and pursuant to a rule promulgated under section 4 of the Act, as required by § 725.25(f).

(8) The submitter does not submit data which the submitter believes show that the microorganism will not present an unreasonable risk of injury to health or the environment, if EPA has listed the microorganism under section 5(b)(4) of the Act, as required in § 725.25(g).

(9) For MCANs, the submitter does not remit the fees required by § 700.45(b)(1) or (b)(2)(vi) of this chapter.

(b)(1) If EPA receives an incomplete submission under this part, the Director, or a designee, will notify the submitter within 30 days of receipt that the submission is incomplete and that the review period will not begin until EPA receives a complete submission.

(2) If EPA obtains additional information during the review period for any submission that indicates the original submission was incomplete, the Director, or a designee, may declare the submission incomplete within 30 days after EPA obtains the additional information and so notify the submitter.

(c) The notification that a submission is incomplete under paragraph (b) of this section will include:

(1) A statement of the basis of EPA's determination that the submission is incomplete.

(2) The requirements for correcting the incomplete submission.

(3) Information on procedures under paragraph (d) of this section for filing objections to the determination or requesting modification of the requirements for completing the submission.

(d) Within 10 days after receipt of notification by EPA that a submission is incomplete, the submitter may file written objections requesting that EPA accept the submission as complete or modify the requirements necessary to complete the submission.

(e)(1) EPA will consider the objections filed by the submitter. The Director, or a designee, will determine whether the submission was complete or incomplete, or whether to modify the requirements for completing the submission. EPA will notify the submitter in writing of EPA's response within 10 days of receiving the objections.

(2) If the Director, or a designee, determines, in response to the objection, that the submission was complete, the review period will be deemed suspended on the date EPA declared the submission incomplete, and will resume on the date that the submission is declared complete. The submitter need not correct the submission as EPA originally requested. If EPA can complete its review within the review period beginning on the date of the submission, the Director, or a designee, may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

(3) If the Director, or a designee, modifies the requirements for completing the submission or concurs with EPA's original determination, the review period will begin when EPA receives a complete submission.

(f) If EPA discovers at any time that a person submitted materially false or misleading statements in information submitted under this part, EPA may

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find that the submission was incomplete from the date it was submitted, and take any other appropriate action.

### § 725.36 New information.

(a) During the review period, if a submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the MCAN or exemption request, the submitter must send that information to the address listed in § 725.25(c) within 10 days of receiving the new information, but no later than 5 days before the end of the review period.

(b) The new submission must clearly identify the submitter, the MCAN or exemption request to which the new information is related, and the number assigned to that submission by EPA, if known to the submitter.

(c) If the new information becomes available during the last 5 days of the review period, the submitter must immediately inform the EPA contact for that submission by telephone of the new information.

### § 725.40 Notice in the Federal Register.

(a) *Filing of FEDERAL REGISTER notice.* After EPA receives a MCAN or an exemption request under this part, EPA will issue a notice in the FEDERAL REGISTER including the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, the specific microorganism identity listed in the submission will be published in the FEDERAL REGISTER unless the submitter has claimed the microorganism identity confidential. If the submitter claims confidentiality, a generic name will be published in accordance with § 725.85.

(2) The categories of use of the microorganism will be published as reported in the submission unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under § 725.88 will be published.

(3) A list of information submitted in accordance with § 725.160(a), 725.255, 725.260, 725.355, or 725.455, as appropriate, will be published.

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(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

(c) *Publication of exemption decisions.* Following the expiration of the appropriate review period for the exemption request, EPA will issue a notice in the FEDERAL REGISTER indicating whether the request has been approved or denied and the reasons for the decision.

### § 725.50 EPA review.

(a) *MCANs.* The review period specified in section 5(a) of the Act for MCANs runs for 90 days from the date the Document Control Officer receives a complete submission, or the date EPA determines the submission is complete under § 725.33, unless the Agency extends the review period under section 5(c) of the Act and § 725.56.

(b) *Exemption requests.* The review period starts on the date the Document Control Officer receives a complete exemption request, or the date EPA determines the request is complete under § 725.33, unless the Agency extends the review period under § 725.56. The review periods for exemption requests run as follows:

(1) *TERAs.* The review period for TERAs is 60 days.

(2) *TMEs.* The review period for TMEs is 45 days.

(3) *Tier II exemption requests.* The review period for Tier II exemption requests is 45 days.

### § 725.54 Suspension of the review period.

(a) A submitter may voluntarily suspend the running of the review period if the Director, or a designee, agrees. If the Director does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter may request a suspension at any time during the review period. The suspension must be for a specified period of time.

(b) A request for suspension may be made in writing to the address listed in § 725.25(c). The suspension also may be made orally, including by telephone, to the submitter's EPA contact for that submission. EPA will send the submitter a written confirmation that the suspension has been granted.